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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10.009.219	11-07-2001	Walter E. Dewolf	GM50056	5535

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/009,219	<b>Applicant(s)</b> DEWOLF, WALTER E.	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of the Application***

[1] Claims 1-17 are pending in the application.

[2] It is noted that the claims recite an amino acid sequence of SEQ ID NO:4. However, the sequence listing indicates that SEQ ID NO:4 is a nucleic acid sequence of 33 nucleotides.

[3] The information disclosure statement filed as Paper No. 2 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

[4] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### ***Lack of Unity***

[5] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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**Group I**, claim(s) 1-10, drawn to the special technical feature of an antagonist that inhibits an activity of the polypeptide of SEQ ID NO:2 or 4 and the first claimed method of use, i.e., a method for the treatment of an individual having need to inhibit Fab I polypeptide.

**Group II**, claim(s) 1-8, drawn to the special technical feature of an agonist that activates an activity of the polypeptide of SEQ ID NO:2 or 4 and the first claimed method of use, i.e., a method for the treatment of an individual having need to activate Fab I polypeptide.

**Group III**, claim(s) 11-13, 16, and 17, drawn to the special technical feature of a method for inhibiting an activity of a Fab I polypeptide.

**Group IV**, claim(s) 14 and 15, drawn to the special technical feature of a method for inhibiting a growth of bacteria.

[6] The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I and II are an antagonist and an agonist for treatment of a bacterial infection, which is shown by EP 0826774 A2 (cited in the IDS of Paper No. 2) to lack novelty or inventive step because EP 0826774 A2 teaches an antagonist and agonist for treatment of a bacterial infection and does not make them a contribution over the prior art.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The antagonist of Group I and the agonist of Group II do not have unity of invention because the special technical feature of Group I is an antagonist, which is not shared by the special technical feature of Group II.

The antagonist of Group I and the methods of Groups III and IV do not have unity of invention because the antagonist of Group I already includes a method of use, and 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

The agonist of Group II is neither used nor made by the methods of Groups III and IV.

The methods of Groups III and IV do not have unity of invention as the special technical feature of any one of Groups III and IV is not shared by the remaining group.

[7] This application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

**Group a**, uncompetitive inhibition by Apo-ACP versus NADH (Ki(app)).

**Group b**, competitive inhibition by Apo-ACP versus crotonoyl CoA.

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**Group c**, induction of negative cooperativity with respect to CCA binding.  
**Group d**, use of NADH and NADPH as substrates by Fab I.  
**Group e**, binding of NADH and NADPH by Fab I.  
**Group f**, oxidation of NADH and NADPH by Fab I.  
**Group g**, ratio of Kmapp for NADH as compared to NADPH.  
**Group h**, use of NADH and crotonoyl CoA as substrates by Fab I in a sequential kinetic mechanism.  
**Group i**, sequential binding of NADH and crotonoyl CoA by Fab I.  
**Group j**, increasing inhibition of Fab I by saturated fatty acyl CoA's of increasing chain length.  
**Group k**, feedback regulatory mechanism of Fab I by saturated fatty acyl CoA's.  
**Group l**, competitive inhibition by palmitoyl CoA versus crotonoyl CoA.  
**Group m**, competitive inhibition by palmitoyl CoA versus crotonoyl CoA modulation through binding of multiple palmitoyl CoA molecules to Fab I.  
**Group n**, binding of multiple palmitoyl CoA molecules to Fab I.  
**Group o**, negative cooperativity in the binding of CCA.  
**Group p**, formation of a dimeric quarternary structure.  
**Group q**, formation of a tetrameric quarternary structure.  
**Group r**, formation of an oligomeric quarternary structure.  
**Group s**, binding of Fab I by pseudo-product inhibitors beta-NADP+ or palmitoyl coA.  
**Group t**, NADH binding to Fab I prior to or simultaneous with ACP binding.

[8] The following claim(s) are generic: 1-3, 5, 6, 8-12, 14, and 16.

[9] The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Each of Groups a-t is a different activity and thus, the Fab I activities of Groups a-t share no special technical feature.

[10] It is noted that claims 1-17 will be examined only to the extent the claims read on the elected subject matter.

[11] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[12] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

*DS* 07/24/03